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10/040,883	01/07/2002	Robert W. McClane	6300.103	8869

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EXAMINER

ROY, BAISAKHI

ART UNIT PAPER NUMBER

3737

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/040,883

Applicant(s)

MCCLANE ET AL.

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/7/02</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1- 4, 7, 8, 12-15, 17, 27, 30, and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 5, 8, 9, 12, 13, 17, 19, 20, 23, and 26 of U.S. Patent No. 5873831 in view of Treado et al. (2003/0004419). Regarding claims 1, 12, 13, and 27, the patented claims disclose a method and apparatus for measurement of macular carotenoid levels and detection of materials deposited and concentrated in retinal tissue by obtaining a light source generating light at a wavelength that produces a Raman response with a wavelength shift for one or more macular carotenoids to be detected; directing light from the light source onto macular tissue of an eye for which macular carotenoid levels are to be measured; collecting light scattered from the macular tissue, the scattered light including elastically and inelastically scattered light, the inelastically scattered light having a plurality of Raman signals corresponding to the one or more macular

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carotenoids; selectively removing the elastically scattered light; analyzing the spatial position and intensity of the Raman signals in the inelastically scattered light. The patented claims however do not disclose producing an image of the Raman signals. In the same field of endeavor, Treado et al. discloses a method and apparatus for producing an image of the Raman signals, the image representing the spatial distribution and concentration level of the one or more macular carotenoids in the macular tissue (abstract, [0015], [0016], fig. 1c, 2c, 2d, 3c, 3d, [0035], [0048], [0053], and claims 1, 2, 16, 23, 24). It would have therefore been obvious to one of ordinary skill in the art to use the Raman signal imaging teaching by Treado et al. to modify the patented claims of ('831) for the purpose of imaging the spatial distribution and concentration level of macular carotenoids. Regarding claims 2 and 14, the patented claims 3 and 20 disclose a method and apparatus of generating light at a wavelength that overlaps the absorption bands of the of one of more macular carotenoids to be detected. Regarding claims 3, 15, and 30, the patented claims 2, 13, and 19 teaches said method and apparatus to include said light source generating light at a wavelength range between 350 nm to about 550 nm. Regarding claim 4, the patented claim 9 teaches said method to include light source intensity that does not destroy the macular tissue and alter carotenoid levels. Regarding claims 7 and 8, the patented claims 4 and 8 disclose said method to include macular tissue residing in a live subject and where the inelastically scattered light is analyzed at frequencies characteristic of macular carotenoids. Regarding claim 17, the patented claim 23 teach a light exposure time of ten seconds which lies in the interval of 0.001 to 100 seconds as disclosed in the

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application claim. Regarding claim 31, the patented claim 26 teaches said apparatus to include a fiber optic bundle.

3. Claims 11, 13, 20, 22, 23, 27, 32-34, 37, 38, 39, 43, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 22, 26, and 28-32 of U.S. Patent No. 6205354 in view of Treado et al. Regarding claims 11, 13, and 27, the patented claims 1 and 22 disclose a method and apparatus for determining the distribution and concentration of carotenoids in biological tissue by obtaining a light source generating light at a wavelength that produces a Raman response with a wavelength shift for one or more macular carotenoids to be detected; directing light from the light source biological tissue for which macular carotenoid levels are to be measured; collecting light scattered from the biological tissue, the scattered light including elastically and inelastically scattered light, the inelastically scattered light having a plurality of Raman signals corresponding to the one or more carotenoids; selectively removing the elastically scattered light; analyzing the spatial position and intensity of the Raman signals in the inelastically scattered light. The patented claims however do not disclose producing an image of the Raman signals. In the same field of endeavor, Treado et al. discloses a method and apparatus for producing an image of the Raman signals, the image representing the spatial distribution and concentration level of the one or more carotenoids in biological tissue (abstract, [0015], [0016], fig. 1c, 2c, 2d, 3c, 3d, [0035], [0048], [0053], and claims 1, 2, 16, 23, 24). It would have therefore been obvious to one of ordinary skill in the art to use the Raman signal imaging teaching by Treado et al. to modify the patented claims

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of ('831) for the purpose of imaging the spatial distribution and concentration level of carotenoids in biological tissue. Regarding claims 20, 22, 23, 39, 43, and 44, the patented claims 29-32 teach said detection and analysis apparatus to include a charge coupled device camera, a computer, and a visual display monitor. Regarding claim 38, the patented claim 28 teaches said system to include an acousto-optic filter. Regarding claims 32-34, and 37, the patented claims 22 and 26 teach said apparatus to include a collimating condenser lens, a band pass filter, and a dichoric or holographic beam splitter and further includes a lens to focus light onto the tissue and collect light scattered back from the tissue, a scanning-type instrument, and a narrow band filter.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 5, 6, 9-11, 13, 16-26, 27, 31, 35-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Rava et al. (6690966).

Regarding claims 1, 11, 13 and 27, Rava et al. discloses an imaging method and apparatus for determining the distribution and concentration of carotenoids in biological tissue by obtaining a light source generating light at a wavelength that produces a Raman response with a wavelength shift for one or more carotenoids to be detected; directing light from the light source biological tissue for which carotenoid levels are to be measured; collecting light scattered from the biological tissue, the scattered light including elastically and inelastically scattered light, the inelastically scattered light having a plurality of Raman signals corresponding to the one or more carotenoids; selectively removing the elastically scattered light; analyzing the spatial position and intensity of the Raman signals in the inelastically scattered light; producing an image of the Raman signals through an output means (col. 2 lines 42-59, col. 5 lines 25-67, col. 6 lines 1-22, col. 7 lines 20-31 lines 50-67, col. 10 lines 47-52, col. 26 lines 28-50, and claims 1-16).

Regarding claims 5 and 16, Rava et al. teaches said light source to generate light at an exposure spot size of between 5 microns to 10 mm (col. 7 lines 50-53).

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Regarding claims 6 and 17, Rava et al. further teaches said method to include generating light with an exposure time of about 0.001 to about 100 seconds (col. 25 lines 6-9, claims 12-14).

Regarding claims 18, 19, 35, and 36, Rava et al. further teaches said apparatus to include wavelength selective means being adapted to be angle tuned to transmit Raman shifted light at an on peak position or transmit light at an off peak position (col. 7 lines 20-31). Rava et al. further teaches said apparatus to include wavelength selective devices comprising of interference filters (col. 7 lines 50-67).

Regarding claims 20 and 39, Rava et al. further teaches said apparatus to include an optical detector array on a charge coupled device camera (col. 3 lines 36-54).

Regarding claims 21, and 40-42, Rava et al. teaches said apparatus to include a discrete photo detector consisting of a photomultiplier tube or a photodiode with an aperture in front of the photo detector for focusing the Raman scattered light from the macular tissue onto the photo detector (col. 5 lines 56-65, fig. 1c).

Regarding claims 9, 10, 22-26 and 43-45, Rava et al. teaches said apparatus and method to include data processing device comprising a computer, a visual display means, means for printing said display, producing an output image as an en face map, and as a topographical surface plot (col. 5 lines 51-67, col. 6 lines 1-9, fig. 2-15, 19-21).

6. Claims 1, 9-11, 13, 20, 25-27, 31, 35, 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Treado et al.



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Regarding claims 1, 11, 13, 27, and 31, Treado et al. discloses an imaging method and apparatus for determining the distribution and concentration of carotenoids in biological tissue by obtaining a light source generating light at a wavelength that produces a Raman response with a wavelength shift for one or more carotenoids to be detected; directing light from the light source onto biological tissue via fiber optic bundle; collecting light scattered from the biological tissue, the scattered light including elastically and inelastically scattered light, the inelastically scattered light having a plurality of Raman signals corresponding to the one or more carotenoids; selectively removing the elastically scattered light; analyzing the spatial position and intensity of the Raman signals in the inelastically scattered light; producing an image of the Raman signals through an output means (abstract, [0015], [0016], [0031-0035], [0048], [0084], and claims 1, 2, 5, 16, 23, 24, 27, 37).

Regarding claims 9, 10, 25, and 26, Treado et al. teaches said Raman imaging method and apparatus to include output means by generating maps of surfaces ([0035]).

Regarding claims 20 and 39, Treado et al. further teaches said apparatus to include an optical detector array on a charge coupled device camera ([0032-0035]).

Regarding claim 19, Treado et al. teaches transmitting Raman shifted light at on peak and off peak wavelength positions ([0031-0032]).

Regarding claim 38, Treado et al. teaches said wavelength selective device to be an acousto-optic filter ([0036]).

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Regarding claims 22, 23, 43, and 44, Treado et al. teaches said data processing device to comprise of a computer and a display monitor ([0048], [0057], [0060]).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3, 15, 24, 35, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treado et al. in view of Alfano et al. (5348018).

Regarding claims 3 and 15, Treado et al. does not teach a specific wavelength range of the light source to determine tissue malignancy. Alfano et al. discloses an imaging method with a light source with wavelength in the 350-550 nm range to determine tissue malignancy (col. 3 lines 34-68, col. 4 lines 1-5, and claims 1, 3-5, 11-13, 16). It would have therefore been obvious to one of ordinary skill in the art to use the wavelength range teaching by Alfano et al. in the teaching by Treado et al. for the purpose of generating light at a wavelength range corresponding to the absorption characteristics of carotenoids.

Regarding claims 24 and 45, Treado et al. does not explicitly teach said output device to include a printer. Alfano et al. teaches an output device to include a printer (col. 7 lines 27-45). It would have therefore been obvious to one of ordinary skill in the art to use the printer teaching by Alfano et al. in the teaching by Treado et al. for the purpose of generating a hard copy of the results.

Regarding claim 35, Treado et al. teaches the use of multiple interference filters ([0084]) but does not explicitly teach the use of narrow and broad band interference filter. Alfano et al. teaches the use of narrow and broad band interference filter (col. 7 lines 5-16, col. 8 lines 41-55). It would have therefore been obvious to one of ordinary skill in the art to use the filter teaching by Alfano et al. in the teaching by Treado et al. for the purpose of using a wavelength selective device to select Raman shifted light from the collected scattered light.

9. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al. in view of Verma (4832483). Rava et al. teaches said apparatus to include a light source such as a laser but does not explicitly teach an argon ion laser or a mercury ion lamp. Verma discloses a Raman imaging method to evaluate biological samples with a light source such as a mercury arc lamp or an argon ion laser (col. 7 lines 32-37, col. 8 lines 39-51). It would have therefore been obvious to one of ordinary skill in the art to use the light source teaching by Verma in the teaching by Rava et al. for the purpose of generating light in a wavelength that overlaps the absorption bands of the carotenoids of interest.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.R.

BR

  
ELENI MANTIS-MERCADER  
PRIMARY EXAMINER